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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,289	08/10/2000	Volker Landschutze	514413-3834	7068

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/636,289	LANDSCHUTZE, VOLKER	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on papers filed 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-12,15,19,22-24,29,31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-12,15,19,22-24,29,31 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 2, penultimate line of the preamble, where "comprising" should be changed to -- comprises-- , and in the body of the claim, where each recitation of "encode" or "lead" should be replaced with --encodes-- or -- leads-- ; in claim 10, line 4, where "molecules" should be replaced with -- molecule --; in claim 23, where "claims" should be replaced with -- -- claim-- --; in claim 34, where each recitation of "encode" or "lead" should be replaced with --encodes-- or -- leads-- ; and in claim 36, line 5 where "molecule leads" should be replaced with -- -- molecules lead-- --; and in claim 36, parts (i)-(iv), where each recitation of "encode" or "lead" should be replaced with --encodes-- or -- leads--.

Claim 15 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiply dependent claim. See MPEP § 608.01(n). In the interest of compact prosecution, the claim has been treated on the merits. Such treatment does not relieve Applicant of the responsibility to respond to this objection.

The amendments of 30 October 2003 and accompanying arguments have overcome the outstanding indefiniteness and art rejections. Claims 1-2, 7-12, 15, 19, 22-24, 29, 31 and 33-37 are pending.

Claims 1, 7-12, 15, 19, 22-24, 29, 31 and 33 (newly amended) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out

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and distinctly claim the subject matter which applicant regards as the invention.

Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of "one foreign nucleic acid molecule...selected from the group consisting of a) DNA molecules..." which is confusing and contradictory.

Claims 1, 8, and 10 are indefinite in their recitation of "antisense RNA ... which lead via a cosuppression effect" which is confusing, since cosuppression is caused by sense RNA molecules.

Claims 1-2, 7-12, 15, 19, 22-24, 29, 31 and 33 remain, and new claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 3 of the last Office action for claims 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33.

Claims 1-2, 7-12, 15, 19, 22-24, 29, 31 and 33 remain, and new claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to nucleic acid constructs comprising at least 1330 base pairs of the potato GBSSI gene and the entire coding sequence of the potato BEI gene, each in antisense orientation with respect to its own promoter, does not reasonably provide enablement for claims broadly drawn to plant transformation with a single gene encoding a single antisense RNA or a single sense RNA which somehow reduces the

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expression or activity of both GBSSI and BEI, genes which encode or reduce the expression of any type of BE (claim 1), or a single gene encoding both GBSSI and BE (claim 1, part a). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 3 of the last Office action for claims 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33.

Applicant's arguments filed 30 October 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description and enablement rejections are improper, given the recitation in the specification of the use of double constructs or cotransformation or supertransformation, and the assertions in the specification that fragments of the coding sequences can be used for antisense effects

The Examiner maintains that the claims are not limited to the use of double constructs or cotransformation or supertransformation. Additionally, the claims are not limited to the use of the potato GBSSI gene or the potato BEI gene for antisense inhibition or sense cosuppression of the expression of the corresponding genes. Instead, claims 1, 7-12, 15, 19, 22-24, 29, 31 and 33 are drawn to the use of single nucleic acid sequences from any gene source and from any plant source which somehow simultaneously reduce the expression of both GBSSI *and* BE proteins, often by both antisense and cosuppression effects simultaneously. Additionally, these claims as well as claims 34-37 are broadly drawn to DNA molecules of any sequence and from any plant or gene source which somehow reduce expression of either GBSSI or BE

proteins, via antisense or cosuppression effects. Furthermore, the body of each claim recites the inhibition of any BE protein, rather than BEI.

Regarding enablement, no guidance is presented in the specification for a multitude of DNA sequences from a multitude of gene sources and a multitude of plant sources which somehow are able to inhibit the expression of potato GBSSI or BE proteins. Applicant's assertions are insufficient to overcome the Examiner's cited evidence of unpredictability. It is further noted that Applicant's arguments are not commensurate with what is actually being claimed.

Regarding written description, no guidance is provided regarding the conserved structural features of this broadly claimed genus which would be responsible for the claimed function, as required by MPEP 2163 and the Revised Written Description Guidelines cited previously.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 5, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a stylized flourish at the end.